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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,442	03/05/2001	Tsuneo Takahashi	99-1043-US	1333

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YOUNG & THOMPSON  
745 SOUTH 23RD STREET 2ND FLOOR  
ARLINGTON, VA 22202

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/786,442

Applicant(s)

TAKAHASHI ET AL.

Examiner

Robert Landsman

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/30/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-12 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s)        are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on        is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No.       .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s)       .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Sequence Comparisons A-C*.

## DETAILED ACTION

### *1. Formal Matters*

- A. The Information Disclosure Statement, filed 6/5/01, has been entered into the record.
- B. Claims 1-24 are pending in this application and subject to restriction in Paper No. 10, dated 9/30/02. In Paper No. 11, Applicants elected Group I, claims 1-11 and 23 with traverse. Applicants argue that the same claims in this application were subject to examination during the international phase of the PCT application and that the international Examiner found no lack of unity and that the present Action does not explain why, applying the same legal standard, a conflicting result is being reached in the present case. Applicants also argue that the citation of a reference is required in order to make a lack of unity. Applicants' arguments have been considered, but are not deemed persuasive.

First, respectfully, the Examiner does not need to explain why an opposite result from that of the International Examiner is being reached. The US Examiner does not know the reasons for the International Examiner not finding a lack of unity. However, the finding of a lack of unity is at the discretion of the Examiner, as is the case for US restriction practice. Furthermore, there is no requirement for a citation to be used to make a showing of lack of unity. However, upon further consideration, the Examiner has decided to combine Group II, claims 12 and 24 with Group I. Therefore, claims 1-12, 23 and 24 are the subject of this Office Action. This lack of unity has been deemed proper and is, therefore, made FINAL.

### *2. Specification*

- A. The specification is objected to since the Oath/Declaration states that this application is a 371 of PCT/JP99/04801. However, this priority data is not recited in the first line of the specification.

### *3. Claim Objections*

- A. The syntax of claim 8 can be improved by amending the claim to recite "any one of claims 3, 4, 5 or 6."
- B. The syntax of claim 10 can be improved by replacing the word "obtainable" with "prepared."
- C. The syntax of claim 24 can be improved by removing the second recitation of "or the peptide of claim 2."

**4. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated DNA of SEQ ID NO:3 and 4, does not reasonably provide enablement for “derivatives thereof” of SEQ ID NO:3 or 4, or DNA which encodes at least 12 contiguous nucleotides of SEQ ID NO:3 or 4, or peptides comprising at least 5 contiguous residues of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all “**derivatives thereof**” of SEQ ID NO:3 or 4, or DNA which comprises “**at least 12 contiguous nucleotides**” of SEQ ID NO:3 or 4. A derivative or fragment of SEQ ID NO:3 or 4 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:3 or 4 and encode for a protein with one or more substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:2. Similarly, a peptide comprising “**at least 5 contiguous residues**” of SEQ ID NO:2 would have one or more substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:2. Applicants provide no guidance or working examples of derivatives of SEQ ID NO:3 and 4, nor do they provide a *function* of these molecules, or of the proteins which they encode, including those of at least 5 contiguous residues of SEQ ID NO:2. Furthermore, it is not predictable to one of ordinary skill in the art what the function of a derivative of SEQ ID NO:3 or 4, or what the function is of a DNA molecule comprising at least 12 contiguous nucleotides of SEQ ID NO:3 or 4, or of a protein comprising at least 5 amino acids of SEQ ID NO:2. Applicants have not identified the critical residues which are necessary to maintain peptide function other than those comprising the full-length protein.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all “derivatives thereof” of SEQ ID NO:3 or 4, DNA which comprises “at least 12 contiguous nucleotides”

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of SEQ ID NO:3 or 4, or a peptide comprising "at least 5 contiguous residues" of SEQ ID NO:2. There is also a lack of guidance and working examples of these nucleic acid molecules and peptides. These factors, along with the lack of predictability to one of ordinary skill in the art as to what the function of these derivatives and fragments of SEQ ID NO:3 or 4 are, or of the fragments of SEQ ID NO:2, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

**5. Claim Rejections - 35 USC § 112, first paragraph – lack of written description**

A. Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Nucleic acid molecules which are "derivatives" of SEQ ID NO:3 and 4 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotides. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:3 and 4 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

**6. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-4, 8, 10-12, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 recite "substantially" pure. The metes and bounds of the term "substantially" are not known since there is no definition for this term in the claims or specification. Applicants may want to consider using the term "purified" in place of "substantially pure" provided there is basis for this term in the specification.

**7. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 2, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US Patent No. 5,861,272). The claims recite a peptide comprising at least 5 contiguous amino acids of SEQ ID NO:2, vectors, host cells and methods of screening for ligands which bind to said receptor. Li et al. teach a peptide comprising 5 contiguous amino acids of SEQ ID NO:2 (Sequence Comparison A). Li et al. also teach vectors and host cells (column 7, line 37 – column 10, line 52; column 20, line 9 – column 22, line 38) and screening for ligands which bind said receptor (column 10, line 53 – column 12, line 52).

B. Claims 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Alvarez et al. (Immunogenetics 44(6):446-452, 1996). The claim recites an isolated DNA comprising at least 12 contiguous nucleotides of SEQ ID NO:3. Alvarez et al. teach a DNA comprising 17 contiguous nucleotides of SEQ ID NO:3 (Sequence Comparison B). One of ordinary skill in the art would immediately envision the complement of SEQ ID NO:3. Therefore, Alvarez et al. meet the limitation of claim 7.

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C. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Alvarez et al. (Immunogenetics 44(6):446-452, 1996). The claim recites an isolated DNA comprising at least 12 contiguous nucleotides of SEQ ID NO:4. Alvarez et al. teach a DNA comprising 17 contiguous nucleotides of SEQ ID NO:4 (Sequence Comparison C).

#### **8. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarez et al. in view of Sibson et al. The claims recite a vector comprising a fragment of SEQ ID NO:3 or 4, a host cell and a method of making a protein. Alvarez et al. teach a DNA comprising 17 contiguous nucleotides of SEQ ID NO:3 (Sequence Comparison B) and 4 (Sequence Comparison C). Alvarez et al. do not teach vectors, host cells and a method of making the protein. However, Sibson et al. do teach expression vectors, host cells and a method of making the protein (page 7, line 39 – page 9, line 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Sibson et al. by substituting a cDNA in the polycloning region of the vector with the polynucleotide (cDNA) of Alvarez et al. for the purpose of transfecting a host cell as taught by Sibson et al. in view of Sibson et al.'s suggestion that it would be desirable to do so (pages 8-13). One of ordinary skill in the art would have been motivated to make this substitution in order to express the protein encoded by the introduced DNA in a host cell to perform ligand binding and functional assays. There would have been a reasonable expectation of success for a person of ordinary skill in the art to make this invention since these techniques are widely used in the art and are highly successful (Sibson et al., page 10, line 38 – page 12, line 42). The present invention, therefore, is *prima facie* obvious over the above references in the absence of evidence to the contrary.

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**9. Conclusion**

A. No claim is allowable.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.

Patent Examiner

Group 1600

January 08, 2003

A handwritten signature in black ink, appearing to read 'Robert Landsman', is located below the typed name and date.